**Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly**

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In FTC v. Actavis, Inc.,¹ THE COURT, in a 5-3 decision, resolved a Circuit split over the antitrust treatment of “reverse payments” included in agreements to settle the litigation generated by the Hatch-Waxman regulatory scheme.² The Court held that reverse payments would be analyzed under the rule of reason, leaving “to the lower courts the structuring of the present rule-of-reason antitrust litigation.”³ In adopting the rule of reason approach, the Court rejected the use of more administrable per se rules used by some lower courts to evaluate reverse payments.

Specifically, the Court declined to adopt the “scope of the patent test” used by the Eleventh Circuit.⁴ This test recognizes the brand firm’s legal ability to use a valid and unexpired patent to prevent entry until the expiration of the patent. In contrast, the Court found there is “reason for concern that settlements taking this form tend to have significant adverse effects on competition.”⁵ In particular, the Court suggested that an otherwise unexplained large reverse payment “likely seeks to prevent the risk of competition. And . . . that consequence constitutes the relevant anticompetitive harm.”⁶ The Court also declined the FTC’s invitation to apply to settlements involving such payments a rule of per se illegality or, alternatively, to subject them to a “quick look” analysis in which such settlements would be presumptively unlawful.⁷

This article examines the economics of litigation and settlement of patent disputes arising from Paragraph IV Abbreviated New Drug Application (ANDA) filings under the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) within the framework set out in *Actavis.* Recent economic analyses of reverse payment settlements demonstrate how agreements to settle patent litigation that delay the date of generic entry beyond the litigation-adjusted expected life of the patent reduce consumer welfare. An important implication of these models is that settlements must reduce consumer welfare if the size of the reverse payment exceeds the patentee’s litigation costs.⁸ These analyses have been used to support antitrust rules that would prohibit reverse payments that exceed the cost of litigation.⁹

This article builds upon these analyses by taking into account important institutional features of the Hatch-Waxman Act’s regulatory regime and of procedural law. Our analysis incorporates the rapid entry by multiple firms that often follows the invalidation of a patent and the expiration of the marketing exclusivity period.¹⁰ Instead of a single entrant obtaining duopoly profits for the remaining life of the patent, as is assumed in prior analyses,¹¹ the generic entrant that successfully challenges the validity of the patent typically obtains duopoly profits only for the 180-day exclusivity period provided by the Act. After this period, both the brand firm with the invalidated patent and the generic entrant that invalidated the patent face additional generic entrants and, consequently, earn lower profits than they earned during the duopoly period. This typical pattern is the joint product of the Hatch-Waxman Act and the doctrine of collateral estoppel under Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation,¹² which prevents the brand firm with an invalidated patent from relitigating the validity of the patent.

Accounting for this critical institutional detail has important and different implications for patent settlements, welfare, and application of the rule of reason pursuant to *Actavis.* Our analysis of the multi-entrant model implies the payoff for the generic entrant that files the first Paragraph IV ANDA and invalidates the patent is smaller than the monopoly-to-duopoly litigation payoffs generated in the single-entrant models. This reduced payoff decreases the incentive for the entrant to litigate and, likewise, the amount for which it will settle. Litigating a patent under a rule of defensive non-party non-mutual collateral estoppel imposes greater losses upon the patentee than is the case when there is a single entrant. This, in turn, increases the litigation risk the patentee faces and, likewise, the amount it will pay to settle. Compared to the single-entrant model, the result is a significantly broader range of settlements in which the brand and generic entrant have legitimate incentives to settle the case other than “to prevent the risk of competition,” which is “the relevant anticompetitive harm.”¹³

This broad settlement range renders ineffective attempts to regulate the size of patent settlements or to infer a settlement is anticompetitive based solely upon its size. Incorpo-
rating multiple entrants also changes the direct relationship between the litigation-adjusted expected life of the patent and consumer welfare and, most important, weakens the relationship between the strength of the patent and the size of the settlement, which relationship has underlain calls to deem presumptively unlawful all payments greater than anticipated litigation costs. Thus, using litigation cost as an indicator of an anticompetitive settlement would neither induce litigation that would invalidate “bad” patents nor encourage settlements that would increase consumer welfare.

In addition to the positive analysis of litigation, the article examines the alternatives to the static consumer-welfare-only standard used in some analyses to evaluate reverse payment settlements. In this context, a welfare standard that includes more than static consumer surplus should be considered. Settlement avoids the incremental private and social costs of litigation. In addition, the design of the Hatch-Waxman Act, which includes provisions that encourage generic entry and patent term restoration, embodies the tradeoff between producers’ incentive to innovate and consumers’ need for access that is a central focus of the economic analysis of intellectual property rights.

The Single-Entrant Model and the Litigation Cost Benchmark

The single-entrant models provide analytical support for the Court’s inference that reverse payments greater than anticipated litigation costs are likely to harm competition.

Market Structure and Profits under the Single-Entrant Model. Litigation under the Hatch-Waxman Act begins when a generic entrant files an ANDA with a Paragraph IV Certification that the brand firm’s unexpired patent is either invalid or would not be infringed. The filing of a Paragraph IV ANDA creates an act of infringement that allows the patentee to file an infringement suit.

The single-entrant model is a special case of the more general model we discuss below. In particular, the single-entrant model makes the simplifying assumption that the first ANDA entrant that invalidates the brand patent obtains duopoly profits until the patent expires. The undiscounted profits in this model are illustrated in Figure 1. The vertical axis measures profits and the horizontal axis measures time, in years. The top panel shows the post-litigation profits for the Brand and the Generic if the Brand wins, which occurs with probability \( p \). Specifically, the Brand obtains monopoly profits \( \pi^M \) until the patent expires at time \( T \). The middle panel shows the post-litigation profits if the Generic wins, which occurs with probability \( 1-p \). The middle panel in particular shows the effect of the single-entrant assumption. Instead of a short period of duopoly followed by free entry when the patent is invalidated, the single-entrant model generates duopoly profits \( \pi^D \) from the time the patent is invalidated until the time at which the patent would have expired.

Instead of litigating to judgment, the Brand and the generic entrant can settle the case. The terms of the settlement include a reverse payment \( X \) and an agreed upon early entry date \( E \) that is on or before the patent expiration date \( T \). The bottom panel shows the profits from settlement: the Brand enjoys monopoly profits \( \pi^M \) until the Generic enters at time \( E \). The Brand and the Generic obtain duopoly profits \( \pi^D \) from \( E \) until the patent expires, after which they obtain only free entry profits \( \pi^C \).

Feasible Settlements in the Single-Entrant Model. Figure 2 illustrates the set of feasible settlements generated by the single-entrant model when both the Brand and the generic entrant estimate the probability the patent will be upheld (\( p \)) is relatively high, here 0.9. The vertical axis measures the size of the reverse payment \( X \) in dollars, and the horizontal axis measures the date of early entry \( E \) in years. The set of feasible settlements are those both the Brand and the Generic prefer to litigation. They lie in the shaded area between the Brand’s minimum acceptable entry date line and the Generic’s maximum acceptable entry date line. As shown in other papers, absent antitrust constraints on set-
litigation. Entry date equals the litigation-adjusted life of the patent when the size of the reverse payment equals the Brand’s litigation costs. Moreover, any feasible settlement in which the reverse payment exceeds the Brand’s litigation costs must reduce consumer welfare. In that analysis, therefore, a necessary but not sufficient condition for a feasible settlement to increase consumer welfare is that the size of the reverse payment be less than the Brand’s litigation costs.

A rule that limits the size of reverse payments to no more than the Brand’s litigation costs, however, will not necessarily generate settlements that increase consumer welfare relative to the expected welfare generated through litigation. Equilibrium settlements under such a rule, which result in reverse payments equal to the Brand’s litigation costs, will necessarily result in entry dates that are later than the litigation-adjusted life of the patent.

In addition, limiting the size of reverse payments to the Brand’s litigation costs can prevent a settlement that would result in litigation costs savings greater than any loss in consumer welfare. For example, under the parameters in Figure 2, the break-even entry date that increases the sum of consumer welfare plus avoided litigation costs ($E^*$) is 9.254 years.

Although litigation will force the parties to incur higher costs and can lower consumer welfare net of litigation costs, it is important to note that the absence of a settlement is not necessarily a “failure.” In patent litigation, whenever a judgment correctly invalidates or correctly upholds a patent, it produces benefits that generally inure to non-parties, including other generic entrants and consumers. It follows that the welfare associated with a judgment can be greater than the welfare associated with a settlement. The benefits to non-parties, however, are not taken into account in the single-entrant model, which is another reason to move the analysis beyond the temporary duopoly assumption in such models.

### A Model of Litigation and Settlement Under Hatch-Waxman and Blonder-Tongue: Accounting for Multiple Generic Entrants
The single-entrant model does not account for key institutional features of the Hatch-Waxman Act and of Blonder-Tongue that render the post-invalidation duopoly assumption unrealistic when there are multiple entrants. In this section, we set out a more general model of litigation and settlement under the Hatch-Waxman Act that explicitly accounts for the effect of these institutional features.

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**Figure 2: Feasible Settlements in the Single-Entrant Model**

The dark shaded triangle in Figure 2 shows the set of feasible settlements that also increase consumer welfare. In theory, an antitrust rule that required settlements to allow entry on or before the expected patent life could be used to promote consumer welfare increasing settlements. As the Court recognized in *Actavis*, the problem with such a rule is that assessing the strength of a patent would ordinarily require a costly inquiry into the validity of the patent.

The Court and economic analysts have focused upon the size of the Brand’s avoided litigation costs as a more observable proxy for strength of its patent. Under the assumptions of the single-entrant model, the Brand’s minimum acceptable entry date equals the litigation-adjusted life of the patent when the size of the reverse payment equals the Brand’s litigation costs.
Market Structure and Profits Under Hatch-Waxman and Blonder-Tongue. Figure 3 modifies Figure 1 to show the effects of multiple generic entrants. Assuming that the patent will not be challenged if the first ANDA entrant fails to invalidate the patent, the settlement profits of the Brand and of the Generic, depicted in the bottom panel of Figure 3, are identical to those depicted in Figure 1.24 The profits depicted in the top panel of Figure 2, which show the profits when the Brand plaintiff successfully defends the patent, are also identical to those depicted in Figure 1. As a result, the Brand makes monopoly profits \( \pi_M \) during the remaining life of the patent (from time 0 to time \( T \)).

Relaxing the assumption of the single-entrant model changes the middle panel in Figure 3, which shows the payoffs when the first generic entrant invalidates the Brand’s patent.25 Our model accounts for two additional features of the process: the litigation stay and the limited period of exclusivity. If the Brand files an infringement suit within 45 days of the ANDA filing, then FDA action on the ANDA is stayed for 30 months, during which the Brand will continue to make monopoly profits (from time 0 to time \( S \)).26 The first generic to file a Paragraph IV certification is entitled to 180-day marketing exclusivity under some circumstances, including when the patent is invalidated in litigation.27 Thus, when the first generic entrant to file a Paragraph IV ANDA invalidates the Brand’s patent through litigation, the Hatch-Waxman regulatory regime produces a six-month period of duopoly competition between them. Both the Brand and the first generic earn duopoly profits \( \pi_D \) during the period of marketing exclusivity from time \( S \) to time \( S+H \) in Figure 3.

Hatch-Waxman and Blonder-Tongue. For simplicity and for a more direct comparison to the single-entrant model, we assume, as that model does, that the discount rate is zero, and we abstract away from the litigation stay.28 The examples in this section, however, explicitly take into account the effect of the limited 180-day marketing exclusivity period \( H \) and the potential for additional generic entry once a patent has been invalidated and this exclusivity period has ended.

Figure 4 depicts the greater range of feasible settlements in the case where both parties estimate that \( p = 0.9 \) and where both expect three additional entrants will enter if the patent is invalidated or expires.31 Taking into account the effect of collateral estoppel and free entry after the invalidation of a patent expands the set of feasible settlements. Collateral estoppel imposes additional litigation losses on the Brand and shifts its earliest acceptable entry date to the left. The litigation payoff for the first generic entrant to file a Paragraph IV ANDA is lowered because it obtains duopoly profits only for the duration of the 180-day period of market exclusivity and lower free entry profits afterwards. This shifts the first generic’s maximum acceptable entry date to the right.

Equilibrium Settlement and Welfare with the Multiple-Entrant Model. Figure 4 shows the conditions under which a settlement increases consumer welfare compared to the expected consumer welfare net of litigation costs that would be generated through litigation. Such settlements would have to specify an early entry date \( E \) that is earlier than \( E^* \).32 The breakeven entry date \( E^* \) with multiple entrants is earlier than the breakeven entry date generated by the single-entrant model, and earlier than the expected patent life (\( p T \)).
Under the conditions depicted in Figure 4, $E^* = 8.16$. Intuitively, the breakeven date for early entry ($E^*$) is earlier than under the single-entrant model because litigation that results in the invalidation of the patent will produce a greater static expected welfare gain with multiple entrants; instead of resulting in a duopoly for the remainder of the patent life, invalidation of the patent produces six months of duopoly followed by the higher static welfare produced under free-entry competition. Therefore, if settlements are to increase consumer welfare, they must allow entry at a time earlier than the litigation-adjusted life of the patent in order to offset the costs associated with erroneously allowing invalid patents to remain in force (Type II error costs). The Court rejected this approach, expressly out of concern over the possibility of Type II errors. In particular, the Court noted that an important “patent-related policy” is to “eliminate unwarranted patent grants so the public will not continually be required to pay tribute to would-be monopolists without need or justification.”

The bright line rule advocated by some—per se condemnation of reverse payments—would have protected against Type II errors and increased the costs of Type I errors when valid patents were challenged. The Court, recognizing the legitimate value of settling litigation, as well as the complexities involved in the antitrust evaluation of reverse payment settlements, also rejected the bright line rule of per se illegality and the somewhat less error-prone quicklook rule with a presumption of illegality.

The challenge that remains for the lower courts is to fashion a relatively accurate and administrable procedure

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**Figure 4: Feasible Settlements and Welfare in the Multiple-Entrant Model**

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under the rule of reason that minimizes the sum of error costs and direct costs. 40 One possibility would be to embed an inquiry into the validity of the patent as part of the antitrust case. 41 In theory, if this inquiry enabled courts accurately to determine the validity of the patent at a low cost, the scope of the patent test could be applied to cases where the inquiry concludes that the patent is valid, while allowing antitrust claims to proceed in cases where the inquiry concludes the patent is not valid.

The uncertainty and cost of “deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task,” led the Eleventh Circuit to adopt the bright line scope of the patent test.42 The rule of reason analysis adopted by the Supreme Court in Actavis likewise avoids an inquiry into the validity of the patent: It is “normally not necessary to litigate patent validity to answer the antitrust question” as such litigation would “prove time consuming, complex, and expensive,” and likely “not be worth that litigation candle.”43

Rather than a full-blown inquiry into the merits of the patent, the Court suggested that the portion of the reverse payment that is not explained by traditional settlement considerations or other procompetitive justifications “can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”44 Focusing upon this surrogate, “a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments.”45

As we demonstrated above, however, even under the assumptions of the single-entrant model, equilibrium settlements can involve very large payments. Even when both parties in the example estimate that the patent will be upheld 90 percent of the time, the range of equilibrium reverse payment settlements is 8 to 12 times each party’s litigation costs. If, perhaps more realistically, both parties estimate the probability of the patent being upheld at only 50 percent, then the range of equilibrium reverse payment settlements is from 7 to 53 times each party’s litigation costs.46 If the patent is valid, the reverse payment is the cost to the Brand of avoiding a Type I error.47 Unconstrained equilibrium settlements allow the Brand to minimize the costs of Type I error. That is, there is always some settlement without early entry that allows the Brand to reduce its costs relative to litigating and an alternative settlement that allows generic entry prior to the expiration of the patent.

If the patent is not valid, then reverse payment settlements impose the highest Type II error costs. Under the assumption that invalid patents do not promote innovation, a settlement that does not allow early entry imposes the deadweight loss from monopoly for the maximum amount of time—the life of the patent—and reduces consumer welfare relative to settlements that allow generic entry before the expiration of the patent.

The positive analysis based upon the multiple-entrant model shows that the competitive setting generated by the Hatch-Waxman regulatory regime and the Court’s collateral estoppel rules work to generate strong incentives for settlement. These incentives are much stronger than the incentives to settle in single-entrant models. Indeed, the multiple-entrant model predicts that litigation of the validity of the patent to judgment is unlikely, and so too, therefore, is the invalidation of bad patents, a “public good” forgone.

Moving to the normative implications of our positive analysis, the multiple-entrant scenario implies that an antitrust rule based upon the size of reverse payments will not produce settlements that increase consumer welfare net of litigation costs. As shown in the example, all feasible settlements, including those with no reverse payments, reduce static consumer welfare as compared to litigation. Indeed, the multiple-entrant model shows the static welfare gains from invalidating a patent are much greater than those generated...
in the monopoly-to-duopoly model. This has led many to advocate a policy that would not only ban reverse payments, but also have courts scrutinize closely all settlements of Hatch-Waxman patent litigation.\footnote{133 S. Ct. 2223 (2013).}

Those more strict limitations upon settlements of Hatch-Waxman patent litigation do not reflect a full error cost analysis, which minimizes the sum of error costs and direct costs. A static consumer welfare standard is incomplete as it ignores direct costs and considers only some of the error costs. More specifically, this standard, at best, provides a proxy for the consumer welfare costs associated with Type II error.


Figure 5 modifies Figure 4 to include that standard. Under a total welfare net litigation costs standard, the breakeven early entry date for a settlement $E^{**} = 8.96$ in the multiple-entrant model. Using this standard, a large range of the feasible set would raise total welfare net of litigation costs.$^{31}$ Indeed, reverse payments as high as $X^M$ can generate total welfare that is greater than the expected total welfare that would be generated through litigation net of litigation costs. In the example depicted in Figure 5, this amount is seven times the Brand’s litigation costs.$^{52}$

The standard of total welfare net of litigation costs shown in Figure 5, which only re-weights the relative importance of litigation costs and of static welfare reducing Type II errors,$^{53}$ still fails to address the costs of “dynamic” Type I errors, i.e., the costs of forgone innovation due to the reduced incentives that result from the erroneous invalidation of patents and the \textit{in terruorem} settlements paid to avoid that outcome.\footnote{FTC v. Watson Pharmcs, Inc., 677 F.3d 1298, 1313 (11th Cir. 2012). See also Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005) (citing Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003) (finding that the appropriate analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects”). This test was also applied by the Second and Federal Circuits. See \textit{In re Ciprofloxacin Hydrochloride Antitrust Litig.}, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (finding no error in the district court’s analysis applying the 11th Circuit’s scope of patent test); \textit{In re Tamoxifen Citrate Antitrust Litig.}, 466 F.3d 187, 207 (2d Cir. 2006) (“[W]e see no sound basis for categorically condemning reverse payments employed to lift the uncertainty surrounding the validity and scope of the holder’s patent.”).}

Considering the full error cost analysis, including the costs of dynamic Type I error, the breakeven early entry date $E^*$ may be even farther to the right of the breakeven point shown in Figure 5. Indeed, because patent terms are not set optimally, but are based upon the arbitrary statutory rule of 20 years from filing, it is possible that a full error cost analysis, taking dynamic Type I errors into account, would find that settlement agreements where generic entry is not allowed before the expiration of the patent in fact increase dynamic welfare, which would support the scope of the patent test. Inasmuch as the regulatory structure of the Hatch-Waxman Act includes patent term restoration, it is odd not to consider the costs of dynamic Type I error in any analysis of the patent/antitrust interface under the statute.

\section*{Conclusion}

In \textit{FTC v. Actavis}, the Court rejected bright line rules of legality and illegality in favor of a standard to be fleshed out by the lower courts applying the rule of reason. At the same time, the Court recognized the costs of an unconstrained rule of reason analysis and suggested a simpler rule—one based upon the size of the brand patentee’s litigation costs—in order to set an antitrust limit on the size of reverse payments. The analysis in this article, which incorporates a model that allows for multiple entrants under Hatch-Waxman, shows such a rule will deem some welfare increasing settlements anticompetitive, encourage litigants to use other, potentially more inefficient means to settle, and increase the costs of dynamic Type I errors.

See Actavis, 133 S. Ct. at 2236–37 (explaining that the size of the unexplained reverse payment can provide “a workable surrogate for a patent’s weakness” and that a large reverse payment creates an inference that the settlement is anticompetitive).

See generally Joseph Farrell & Carl Shapiro, How Strong Are Weak Patents?, 98 AM. ECON. REV. 1347 (2008) (examining the effect of multiple entrants on the incentive to litigate patents generally); Mark R. Patterson, Leveraging Information About Patents: Settlements, Portfolios and Holdups, 50 HOUSE. L. REV. 483 (2012) (analyzing the informational effect of patent challenges and estoppel rules); see also C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1588–94 (2006) (using a model with zero profit competition occurring 180 days after the invalidation of the patent or after entry resulting from settlement of the patent litigation).

See Edlin et al., Actavis and Error Costs, supra note 9, at 1; Harris et al. supra note 9, at 84; see generally Einer Elhauge & Alex Krueger, Solving the Patent Settlement Puzzle, 91 TEX. L. REV. 283 (2012); Murat Mungan, Reverse Payments, Perverse Incentives, 27 HARV. J.L. & TECH. 1 (2013); Carl Shapiro, Antitrust Limits to Patent Settlements, 34 RAND J. ECON. 391 (2003).


Actavis, 133 S. Ct. at 2236.

Figure 2 is based on a figure used by Harris et al., supra note 9, at 87 fig. 3. The example in Figure 2 assumes the demand for the drug is given by \( P = A - BQ \), with \( A = 100 \) and \( B = 1 \). The example also assumes that the costs of litigation over settlement for each party equals \( \$200 \) million per year, drug, then Paragraph IV litigation costs in the example would equal just over \( \$1 \) million. The limits of the bargaining range illustrated in the Figure are explicitly derived in Bruce H. Kobayashi, Joshua D. Wright, Douglas H. Ginsburg & Joanna Tsai, Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly (GMU Law & Econ. Research Paper Series 14-62, 2014), available at http://www.law.gmu.edu/assets/files/publications/working_papers/1462.pdf.

The Brand’s minimum (Generic’s maximum) acceptable entry date contains settling parties patent date and reverse payment (E, X) that make the Brand (Generic) indifferent between litigating and settling. The set of feasible settlements are those that both parties prefer to litigation. Id.

See id. at 7 n.14; Edlin et al., Actavis and Error Costs, supra note 9, at 5.

Edlin et al., Actavis and Error Costs, supra note 9, at 5.

See id.; Shapiro, supra note 12, at 407–08; Mark A. Lemley & Carl Shapiro, Probabilistic Patents, J. ECON. PERSP., Spring 2005, at 75, 94–95.

See Actavis, 133 S. Ct. at 2237.

See id. at 2236 (“Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.”).

This point is made by Harris et al., supra note 9. See also Kobayashi et al., supra note 15, at 8–10 (showing how feasible settlements in the presence of mutual optimism by the parties require reverse payments in excess of litigation costs).

Settlement allows the parties and society to avoid the additional costs of litigating a case to judgment. See generally Robert D. Cooter & Daniel L. Rubinfeld, Economic Analysis of Legal Disputes and Their Resolution, 27 J. ECON. LITERATURE 1067 (1989). These costs are social costs that would be taken into account in a complete error cost analysis. This issue, as well as the problem of measuring welfare appropriately is discussed in more detail below.

See generally Ezra Friedman & Abraham L. Wickelgren, Chilling, Settlement, and the Accuracy of the Legal Process, 26 J.L. ECON. & ORG. 144 (2010) (finding that settlements are not always the best options and that prohibiting settlements in some cases can increase social welfare more than allowing it); Owen M. Fiss, Against Settlement, 93 YALE L.J. 1073 (1984) (arguing that imbalances in resources of the parties can negatively affect the benefits settlements can provide, and that adjudication might sometimes prove to be a better option).

A patent that was upheld in litigation against a generic would-be entrant may be challenged anew by a subsequent generic that files a Paragraph IV ANDA. We assume subsequent ANDA filers will be deterred from filing Paragraph IV ANDAs and entering if the first generic fails to invalidate the patent in litigation. The expected benefits of such a filing for a subsequent potential challenger are reduced for two reasons. First, under Hatch-Waxman a subsequent Paragraph IV ANDA filer does not get a period of market exclusivity. In addition, the persuasive effect of the first case may increase the perceived probability the patent will be upheld in any subsequent case. For a more complete analysis of these issues, see Bruce H. Kobayashi, An Economic Analysis of Reitigation Laws in Intellectual Property Litigation (Working paper, George Mason Law School, May 2014) (on file with author).

The example assumes that \( S = 2 \), not 2.5 years (30 months). This assumes that the parties execute the settlement agreement prior to the expiration of the stay. This might occur, for example, if the parties wanted to avoid the costs of continuing litigation.

If no infringement suit is filed, the FDA can approve the ANDA. The branded firm, however, can then sue the entrant for infringement and, if successful, collect damages based upon the generic entrant’s infringing sales. If the would-be generic entrant does not want to enter without first having invalidated the patent then, following MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007), the generic entrant can file a declaratory judgment action challenging the validity of the patent. See Caraco Pharm. Labs. Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1291–92, 1297 (Fed. Cir. 2008) (citing MedImmune, Inc., 549 U.S. at 126).


Free-entry profits are not zero. The extent of entry will be limited by the costs of entry, which are assumed to be positive. Thus, the model assumes that all firms, including the Brand, make symmetric Cournot profits given N firms, where N is determined by the free entry condition.

For an explicit analysis of these factors, including the effect of positive discount rates, the effect of the stay, and differential estimates of \( p \), see Kobayashi et al., supra note 15.

That is, if the patent is invalided, market competition after the expiration of the Hatch-Waxman 180-day marketing exclusivity period will include 5 firms, viz., the Brand firm (perhaps competing through an authorized generic), the first Paragraph IV generic entrant, and three subsequent ANDA generic entrants.

If litigation costs are not taken into account, the required early entry date would have to be earlier still than \( E^* \).

For a derivation of this threshold and the basis for the numerical example, see Kobayashi et al., supra note 15, 24–26.

Id. at 15–16. (providing an example showing the effects of litigation optimism in the multiple-entrant setting).


See, e.g., Barry Wright Corp. v. ITT Grinnell Corp., 724 F.2d 227, 234 (1st Cir. 1983) (“[U]nlike economics, law is an administrative system the effects of which depend upon the content of rules and precedents only as they are applied by judges and juries in courts and by lawyers advising their clients.”)
Actavis, 133 S. Ct. at 2233 (quoting Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969)).

See, e.g., In re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003) (holding a reverse payment per se unlawful because the agreement “was, at its core, a horizontal agreement to eliminate competition in the market [for the pharmaceutical] throughout the entire United States, a classic example of a per se illegal restraint of trade”); Joshua D. Davis, Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal, 41 RUTGERS L.J. 255, 306 (2009) (arguing reverse payments should be per se unlawful because the “general tendency will be to delay generic entry beyond the expected value entry date, resulting in unnecessary error costs . . . .” and “judicial attempts to scrutinize reverse payments will be unlikely to succeed and will entail substantial transaction costs”).

Actavis, 133 S. Ct. at 2237.


FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012). Turducken refers to a complex culinary dish consisting of a chicken stuffed inside a duck that is stuffed inside a turkey. See Amanda P. Reeves, Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis, ANTITRUST, Fall 2013, at 9, 14 n.40.

Actavis, 133 S. Ct. at 2236.

Id. at 2236–37. The Court noted that the FTC acknowledged reverse payments can have redeeming virtues: “The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.” Id. at 2236.

Id. at 2237.

See Kobayashi et al., supra note 15, at 17 (setting out alternative example where \( p = .5 \)).

In addition, as discussed below, the social costs of Type I error can be larger, and include the forgone benefits of research deterred and of the drugs that would have been produced. In a working paper posted to SSRN as this article goes to press, Edlin et al., suggest that considering costs associated with the erroneous invalidation of valid patents as a Type I error is “erroneous and confusing.” See Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, The Actavis Inference: Theory and Practice, available at http://ssrn.com/abstract=2560107 or http://dx.doi.org/10.2139/ssrn.2560107. In contrast, our view is that consideration of these costs is a critical component of any legal or normative economic analysis of the patent/antritrust interface. As the Court noted: “It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.” United States v. Glaxo Group, 410 U.S. 52, 58 (1973). See generally HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY & CHRISTOPHER R. LESLIE, IP AND ANTITRUST, AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW, SECOND EDITION, Section 1.3 (2014).


These would include the costs imposed upon the court system that are not borne by the parties. In the example, these are assumed to equal the brand’s litigation costs.


With linear demand and constant costs, this result does not depend upon \( p \), the probability that the patent will be upheld in litigation. Under these conditions, changes in \( p \) will shift \( E^* \) and the Brand’s minimum acceptable entry date line to the left by the same amount, leaving \( X^* \) unchanged.

The consumer welfare minus litigation costs standard places greater weight on the reduction of surplus (a cardinal measure) relative to litigation costs than does the total welfare (also a cardinal measure) minus litigation costs standard, which is equivalent to minimizing deadweight loss plus litigation costs.

Indeed, it is interesting that the Court’s opinion in Actavis suggests payment of the Brand’s avoided litigation costs is a legitimate aim of settlement. In other contexts, the extraction of the other parties’ litigation costs has been one of the primary reasons for adopting rules that truncate litigation at an early stage. For example, in moving to a plausibility standard at the pleading stage in Twombly, the Court expressed concern over a plaintiff with “a largely groundless claim” being allowed to “take up the time of a number of other people, with the right to do so representing an in terrorem increment to settlement value.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 558 (2007) (quoting Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 347 (2005)). See also Bruce H. Kobayashi, Law’s Information Revolution as Procedural Reform: Predictive Search as a Solution to the In Terrorem Effect of Externalized Discovery Costs, 2014 U. ILL. L. REV. 1473, 1516 (2014); David Rosenberg & Steven Shavell, A Model in Which Suits Are Brought For Their Nuisance Value, 5 INT’L REV. L. & ECON. 3, 4–6 (1985).